FOR IMMEDIATE RELEASE
November 6, 2007

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**FACT SHEET
INCLUDED

WAXMAN, KENNEDY, ALLEN INTRODUCE BILL TO BOOST FDA'S OVERSIGHT OF OVER-THE-COUNTER DRUGS

WASHINGTON, DC — Today Rep. Henry A. Waxman, Sen. Edward M. Kennedy, and Rep. Tom Allen introduced legislation to increase the ability of the Food and Drug Administration (FDA) to ensure the safety and effectiveness of over-the-counter (OTC) drugs.

The Non-Prescription Drug Modernization Act comes in the wake of a recent FDA advisory panel recommendation that FDA should ban OTC cough and cold medications for children under the age of six. Under current law, if FDA wants to follow its committee's recommendations, FDA would have to go through a lengthy rulemaking process that could take years to complete. Meanwhile, these drugs, for which there is scant evidence of efficacy in children under six, and, in rare cases, could cause serious harm, could continue to be marketed. The Non-Prescription Drug Modernization Act would give FDA the authority to act quickly to protect consumers from unsafe or ineffective OTC drugs, by allowing the agency to revoke authorization to market such drugs without a lengthy rulemaking.

"The pediatric cough and cold medicine debacle has shown us that FDA's authority over OTC drugs is seriously outdated," said Rep. Waxman. "When American consumers buy OTC drugs, they expect them to be safe and to actually work. If we don't get FDA the authority it needs to act quickly, Americans will continue to expose themselves to drugs that may not work, but may pose risks."

"Millions of Americans count on over the counter medicines to keep them healthy, and they deserve to have full confidence that these medicines are safe," said Sen. Kennedy. "That confidence has been shaken by recent revelations that cough and cold medicines may be unsafe for small children. Our legislation strengthens the ability of FDA to protect the health of American families when it finds safety problems with over the counter drugs."

"The basic guiding rule of medicine comes from Hippocrates: 'first, do no harm.' We now know that some widely advertised over the counter cough medicines can pose serious danger to American children." said Rep. Allen. "Our legislation will restore accountability to the process of approving and marketing the medications we give to our

children. It will provide the FDA with the authority and resources it needs to protect our kids and reassure parents that the medicines marketed for children are safe and effective."

The Non-Prescription Drug Modernization Act would also give FDA the authority to regulate OTC drug advertisements. Currently, FDA regulates advertisements for prescription drugs, while the Federal Trade Commission (FTC) regulates advertisements for OTC drugs. Unlike the FDA, FTC is not a public health agency with scientific expertise — it is strictly a law enforcement agency and its enforcement activity in the area of OTC drugs has been minimal. In fact, FTC's most recent enforcement action against an OTC drug advertisement was in 1996. The Non-Prescription Drug Modernization Act would also provide for civil monetary penalties for direct-to-consumer OTC drug advertisement violations.

The bill would also require FDA to report to Congress, after consulting with medical societies and scientists, on whether any of the current OTC drug monographs are in need of review, amendment, or repeal.

A summary and the text of the bill are available online at www.oversight.house.gov.

Fact Sheet

Section-by-Section Summary of The Non-Prescription Drug Modernization Act of 2007

Rep. Henry A. Waxman
Chairman, Committee on Oversight and Government Reform

Section 1: Short Title

The Non-Prescription Drug Modernization Act of 2007

Section 2: Amending or Repealing Monographs

Section 2 provides FDA with explicit expedited rule-making authority to amend or repeal the over-the-counter drug regulations, or "monographs," that set forth the permissible marketing conditions for certain OTC drug products. Traditional rule-making, governed by the Administrative Procedure Act (APA), involves a lengthy process that can take years. Under the APA, before issuing a final rule, federal agencies are first required to issue a proposed rule and allow for a public comment period. Additionally, an agency must publish the final rule 30 days before that rule becomes effective. When FDA has complied with these rule-making procedures, the issuance of final rules typically takes several years, and in some instances has even taken up to 10 years.

The Non-Prescription Drug Modernization Act of 2007 would allow FDA to bypass these procedures and amend or repeal a monograph in a more timely fashion in two circumstances:

1) When FDA, on its own initiative, finds that a monograph must be amended or repealed because a drug under the monograph may pose a significant risk; or

2) After a meeting of one of the Agency's Advisory Committees, when FDA finds that a drug under the monograph lacks evidence of effectiveness.

Section 3: Expansion of FDA's Authority to Regulate Drug Advertising

Section 3 provides FDA with the authority to regulate over-the-counter drug advertisements. Currently, FDA regulates advertisements for prescription drugs, while FTC regulates advertisements for over-the-counter drugs.

Section 3 also amends current law to provide that civil monetary penalties for direct-to-consumer prescription drug advertisement violations (which were recently enacted as part of the FDA Amendments Act of 2007) also apply to violative advertisements of over-the-counter drugs.

Section 4: Identification and Report on Monographs

Section 4 requires FDA to identify whether any current monographs are outdated and therefore in need of amendment or repeal. Specifically, Section 4 requires FDA to open a docket to receive comments from the public, including medical societies and scientists, to gather their views on any changes or updates that should be made to products regulated under FDA's current monograph system. After the comment period has concluded and no later than 2 years after enactment, FDA must report to Congress, identifying any monographs that may require further review to determine whether they should be amended or repealed. FDA's report to Congress must also include an assessment of the resources FDA would need to conduct such a review and make any necessary changes to the monographs, as well as summarize the comments.

Section 5: Authorization of Appropriations

Section 5 would authorize such sums as may be necessary to carry out the Act.